

**This Page Is Inserted by IFW Operations
and is not a part of the Official Record**

BEST AVAILABLE IMAGES

**Defective images within this document are accurate representation of
The original documents submitted by the applicant.**

Defects in the images may include (but are not limited to):

- **BLACK BORDERS**
- **TEXT CUT OFF AT TOP, BOTTOM OR SIDES**
- **FADED TEXT**
- **ILLEGIBLE TEXT**
- **SKEWED/SLANTED IMAGES**
- **COLORLED PHOTOS**
- **BLACK OR VERY BLACK AND WHITE DARK PHOTOS**
- **GRAY SCALE DOCUMENTS**

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

This Page Blank (uspto)

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶: A61B 17/39	A1	(11) International Publication Number: WO 95/05781 (43) International Publication Date: 2 March 1995 (02.03.95)
(21) International Application Number: PCT/US94/08251 (22) International Filing Date: 25 July 1994 (25.07.94) (30) Priority Data: 08/113,441 27 August 1993 (27.08.93) US (71) Applicant: MEDTRONIC, INC. [US/US]; 7000 Central Avenue N.E., Minneapolis, MN 55432 (US). (72) Inventors: MULIER, Peter, M., J.; 1408 Forest Lane, St. Paul, MN 55112 (US). HOEY, Michael, F.; 5733 Pond Drive, Shoreview, MN 55126 (US). (74) Agents: DUTHLER, Reed, A. et al.; Medtronic, Inc., 7000 Central Avenue N.E., Minneapolis, MN 55432 (US).		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>
(54) Title: METHOD AND APPARATUS FOR R-F ABLATION (57) Abstract <p>An ablation catheter and a method of performing cardiac ablation. The catheter is provided with a hollow, helical electrode, which is screwed into cardiac tissue at a desired ablation site and connected to a source of R-F electrical energy to ablate the tissue adjacent the electrode. Prior to ablation, a conductive fluid may be injected through the hollow needle, both to provide for cooling of the tissue adjacent the needle and to increase the conductivity of the tissue in the area of the electrode.</p>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LU	Luxembourg	SN	Senegal
CN	China	LV	Latvia	TD	Chad
CS	Czechoslovakia	MC	Monaco	TG	Togo
CZ	Czech Republic	MD	Republic of Moldova	TJ	Tajikistan
DE	Germany	MG	Madagascar	TT	Trinidad and Tobago
DK	Denmark	ML	Mali	UA	Ukraine
ES	Spain	MN	Mongolia	US	United States of America
FI	Finland			UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

METHOD AND APPARATUS FOR R-F ABLATION

Background of the Invention

5 This invention relates generally to the field of devices for cardiac surgery, and more specifically to devices for R-F ablation of cardiac tissue.

The present invention is directed toward treatment of tachyarrhythmias, which are heart rhythms in which an chamber or chamber of the heart exhibits an excessively fast rhythm. In particular, the present invention is directed toward treatment of tachycardias, which are due to the presence of ectopic foci within the
10 cardiac tissue or due to the presence of aberrant condition pathways within the cardiac tissue.

Therapies have been developed for treating tachycardias by destroying cardiac tissue containing identified ectopic foci or aberrant conduction pathways. A variety of approaches have been taken, including application of electrical energy
15 or other forms of energy to destroy the undesired cardiac tissue. As examples, ablation of cardiac tissue has been accomplished by means of radio frequency electrical current, microwave energy, heat, electrical pulses, cryotherapy, and lasers. At present, ablation using R-F energy is perhaps the most widely practiced in the context of ablation procedures that can be carried out by means
20 of a catheter, inserted into the closed heart.

Most R-F ablation catheters employ electrodes which are intended to contact the endocardium of the heart, or, in some cases as in U.S. Patent No. 5,083,565, are intended to penetrate the endocardium, and enter the myocardium. In general, R-F ablation catheters are effective to induce small lesions in heart
25 tissue including the endocardium and inner layers of myocardium, in the immediate vicinity of the electrode. However, the medical community has expressed a desire for devices which produce larger lesions, to reduce the number of applications of R-F energy (burns) required to effectively ablate the cardiac tissue associated with the tachycardia.

30 R-F ablation causes tissue in contact with the electrode to heat through resistance of the tissue to the induced electrical current therethrough. The actual extent of heating is somewhat unpredictable. However, temperature tends to rise as the duration and amplitude of the R-F signal increase. Heating of the tissue

beyond a certain point can cause dissection or charring of the tissue, resulting in a high impedance between the R-F electrode and the return electrode, which in turn leads to cessation of the heating process, and, in some cases, sticking of the electrode to the charred tissue. One response to this phenomenon has been the inclusion of thermocouple within the ablation electrode, in conjunction with feedback control to modulate the R-F signal to maintain the electrode temperature at a set parameter. One such system is disclosed in U.S. Patent No. 5,122,137.

Summary of the Invention

The present invention is directed toward improving the consistency and efficacy of R-F ablation, and to increase the overall size and extent of the lesions induced by R-F ablation. These goals are pursued by means of an ablation catheter employing a helical electrode intended to be screwed into the myocardium at the site intended for ablation. The helical electrode provides an enlarged surface area as compared to relatively straight or needle-like electrodes for insertion into the endocardium, and also serves to stabilize the location of the catheter during the application of the R-F signal. In addition, there is essentially no bleeding following removal of the helical electrode, so it can safely be placed in multiple locations for mapping and ablation purposes.

An additional aspect of the invention in its preferred embodiment is the provision of a non-toxic, non-arrhythmogenic, conductive solution such as Ringer's solution to the area of the electrode, before and during application of R-F energy. In its preferred embodiment, the helical electrode is hollow, and the conductive solution is applied through one or more apertures in the electrode. The conductive solution injected prior to application of the R-F signal is believed to displace blood in the vicinity of the electrode. Ringer's solution, for example, has a much higher conductivity than blood (approximately 3-4x) or cardiac muscle (approximately 7x), overall resistance to the induced electrical current is reduced, which is believed to assist in expanding the size of the lesion, by spreading the effective area of application of the electrical current over a wider area. Application of the conductive solution during the burn further assists by preventing overheating of the tissue, allowing for a prolonged application of the R-F signal, extending beyond the point at which burning or charring would otherwise normally

occur. Both of these factors are believed to contribute to an increase in the overall size of the lesion produced by application of R-F energy at a particular location.

5 **Brief Description of the Drawings**

Figure 1 is a plan view of a catheter adapted to perform the improved method of R-F ablation, according to the present invention.

Figure 2 is a cutaway view through the distal end of the catheter illustrated in Figure 1.

10 Figures 3, 4, and 5 illustrate alternative embodiments of the helical electrode of the catheter illustrated in Figures 1 and 2.

Figure 6 illustrates the associated apparatus for administration of conductive solution before and during application of R-F energy to the helical electrode.

15

Detailed Description of the Preferred Embodiments

Figure 1 is a plan view of a catheter specifically designed for performing R-F ablation according to the present invention. The catheter includes an elongated catheter body 10, comprising an insulative outer sheath 12, which may be made of polyurethane, teflon, or other biocompatible plastic. A hollow, helical electrode 14 is located at the distal end of the catheter and is coupled to the distal end of an internal tube, running the length of the catheter. At the proximal end of the catheter a fitting 16 is located, to which luer lock 18 is coupled. Luer lock 18 is coupled to the proximal end of the internal tube. A swivel mount 20 is mounted to luer lock 18, allowing rotation of the catheter relative to luer lock 22. Luer lock 22 is intended to be coupled to a source of conductive fluid such as Ringer's solution, and allows for application of the Ringer's solution through the catheter and through electrode 14, while electrode 14 is being screwed into heart tissue. An electrical connector 24 exits fitting 16, and is coupled to electrode 14, allowing for the use of electrode 14 to apply R-F energy to heart tissue. Electrode 14 may also be employed for other related functions such as measurement of electrograms within the heart and pacing of heart tissue by application of low energy pulses appropriate for cardiac pacing. In use, the catheter is advanced

20

25

30

to the desired site for ablation, which preferably has been previously identified by means of cardiac mapping in a fashion similar to cardiac mapping presently employed with R-F ablation procedures. The catheter may be guided to the desired location by being passed down a steerable or guidable catheter, for example, as disclosed in U.S. Patent No. 5,030,204, issued to Badger et al., or by means of a fixed configuration guide catheter, for example in U.S. Patent No. 5,104,393, issued to Isner, both of which patents are incorporated herein by reference in their entireties. Alternatively, the catheter may be advanced to the desired site within a heart by means of a deflectable stylet, as disclosed in PCT Patent Application WO 93/04724, published March 18, 1993, or a deflectable guidewire as disclosed in U.S. Patent No. 5,060,660, issued to Gambale, et al., both of which patents are incorporated herein by reference in their entireties. When the hollow needle 14 is located at the desired location it is screwed into heart tissue by rotating the catheter body. A torque cable within the catheter body provides for 1:1 torque transfer from the proximal end of the catheter to the hollow needle 14.

When advanced to the desired location, luer lock 22 is coupled to a pressurized source of Ringer's solution. An appropriate source is discussed in more detail in conjunction with Figure 6 below. However, for purposes of the present invention, a source of Ringer's solution capable of delivering 1 cc per minute of solution at atmospheric pressure has been found to be adequate. Delivery of Ringer's solution should begin before or at the time at which the electrode 14 is screwed into the tissue to be ablated. In animal experimentation, the inventors have found that delivery of Ringer's solution for a period of two minutes prior to the delivery of R-F energy assists in producing a larger but still controlled, regular lesion.

After the electrode has been located, and Ringer's solution has been administered for the desired period of time, electrical connector 24 is coupled to an R-F electrosurgical power source, of the type commercially available and employed for cutting and electro-coagulation. The present inventors have employed a Blendtome brand electrosurgical generator, Model No. 755, coagulation setting number 7, cutting setting number 1. At these settings, a prolonged application of R-F energy, e.g., one minute or so, may be employed

to produce a large, controlled lesion. Greater or lesser time periods may be employed, however, time periods less than 20 seconds may be counter-indicated, as it appears that the cooling effect of the Ringer's solution, in such shorter R-F application times, may actually decrease the effective size of the lesion.

5 After R-F ablation, the electrode 14 may be coupled to a cardiac pacemaker, and cardiac pacing energy may be delivered to the lesion site in an attempt to measure the pacing threshold. Pacing threshold may be measured by delivering pacing pulses at differing energy levels, e.g. by altering pulse amplitude or width, and determining the minimum energy level effective to cause a
10 depolarization of cardiac tissue. The inventors believe that the higher the pacing threshold, assuming a relatively homogenous lesion, the greater lesion size. As such, the electrode 14 can be used to derive a rough estimate of overall lesion size. The electrode 14 may also be coupled EKG monitoring equipment to assist in determining whether the tachycardia persists and whether the tissue in the
15 vicinity of the electrode is still participating in aberrant conduction or ectopic activity, associated with the tachycardia.

 The helical configuration of electrode 14 is believed to be particularly beneficial in the context of an ablation electrode. Because the electrode is screwed into and completely located within the heart tissue, out of the
20 bloodstream, application of R-F energy is limited to the tissue itself. This differs from traditional R-F ablation electrodes, which simply contact the endocardium, with the result that a substantial portion of the energy applied is dissipated in the blood within the heart adjacent the electrode site. Moreover, R-F energy applied to the bloodstream may cause clotting of the blood adjacent the electrode, and
25 raise the risk of clots breaking loose of the electrode.

 The helical electrode also provides a substantially increased surface area as compared to the needle-like electrodes proposed in the above cited Parins patent, and also serves to anchor the catheter reliably during application of the R-F energy. In addition, the helical shape of the electrode prevents the
30 application of conductive solution through the electrode from causing the electrode to be backed out of its insertion site due to hydraulic pressure, as might occur if a straight, hollow electrode were employed. The elongated path defined

by the helical electrode also reduces the possibility of leakage of conductive fluid along the needle and out of the heart tissue.

Figure 2 illustrates a cutaway version through the end of the catheter illustrated in Figure 1. In this view, it can be seen that helical electrode 14 is provided with an internal lumen 26 which is in communication with the internal lumen of a tube 30. Tube 30 extends to the proximal end of the catheter and is in full communication with luer lock 18, as discussed above, tube 30 may be fabricated of polyimide tubing or of stainless steel tubing. In the present invention, the stainless steel tubing serves as an additional conductor, coupling electrode 14 to electrical connector 24 and enhancing the overall conductivity of the catheter. The use of polyimide tubing, while reducing the overall conductivity of the catheter enhances the flexibility somewhat, and may be beneficial in some cases. It is recommended to apply a steady flow of Ringer's solution through the tubing to electrode 14 during passage catheter through the vascular system to the electrode site, if possible. The flow of Ringer's solution in this case assists in maintaining the patency of the lumen of tubing 30, and prevents plugging of the exit ports of the electrode as it is advanced into the cardiac muscle.

Surrounding tube 30 are two coils 32 and 34, which are wound in opposite directions, to provide a torque cable. In the case of the specific devices employed by the inventors, a torque cable as manufactured by Lake Region Manufacturing Company of Chaska, Minnesota was employed, which torque cable is described in U.S. Patent No. 5,165,421, incorporated herein by reference in its entirety. Coils 32 and 34 also serve as conductors. As illustrated, tubing 30 is between metal coils 32 and 34 and helical electrode 14. However, if polyimide tubing is used, the coils 32 and 34 will serve as the only conductor and thus will be electrically coupled to electrode 14 by means of welding, soldering or mechanical interconnection. Insulative sleeve 12 serves both to provide a smooth exterior for the catheter and to insulate the metal coils 32 and 34, along the length of the catheter.

Figures 3, 4 and 5 illustrate alternate embodiments of the helical electrode illustrated in Figure 2. The electrode in Figure 2 comprises a hollow tube having a single exit port located as its distal end. Electrode 36, illustrated in Figure 3, corresponds to electrode 14 with the exception that additional exit ports 38, 40

and 42 have been added, allowing for dispensing of the Ringer's solution along the length of the helix. Ports 38, 40 and 42 may be laser drilled, and may be spaced in any desired fashion around the circumference of electrode 36 and along the length of electrode 36. Preferably, it is believed desirable to have ports spaced around the full circumference of the electrode, to provide for an even dispensing and dispersing of Ringer's solution.

Electrode 44, illustrated in Figure 4 is a second alternative embodiment of a helical electrode corresponding to electrode 14, but with the addition of an insulative sleeve 46, which covers the proximal portion of the electrode. Sleeve 46 limits the application of R-F energy to the distal portion of the electrode. Optionally, additional exit ports corresponding to ports 38, 40 and 42 illustrated in Figure 43 may also be employed in conjunction with electrode 44. These additional exit ports may be limited to the exposed, uninsulated portion of electrode 44, or may extend along the entire length of electrode 44.

Electrode 48, illustrated in Figure 5 is a third alternative embodiment corresponding generally to electrode 14. However, in this case, electrode 48 is provided with a thermocouple 50 located in the distal end of electrode 48. Thermocouple wires 52 and 54 extend backwards through the lumen within electrode 48 and are used to monitor the temperature at the tip of the electrode, for use in feedback control of power applied to the electrode as described in the above-cited patent issued to Lennox et al. Only one of thermocouple wires 54 and 52 is insulated, and the other is simply coupled to the interior of electrode 48. In order to employ the electrode of Figure 4B, an additional electrical connector would have to be added to the embodiment illustrated in Figure 5, in order to allow connection to the thermocouple wire not connected to electrode 48. Alternatively, both thermocouple wires may be insulated, requiring two additional electrical connectors at the proximal end of the device, each coupled to one of the thermocouple wires. It should be noted that the thermocouple 50 effectively blocks the distal opening of the lumen within electrode 48, so that Ringer's solution will be dispensed only by means of side ports 56, 58 and 60.

Figure 6 illustrates a pressurized source for Ringer's solution which may be employed in conjunction with catheter illustrated in Figure 1. A reservoir 100 is provided, which is commercially manufactured by Block Medical Inc., and sold

under the brand name "Home Pump". The reservoir contains Ringer's solution and provides Ringer's solution at one atmosphere pressure to flow control 102, via filter 104. Flow control 102 may, for example, provide a flow limit of 20 drops or 1 cc per minute. Flow control 102 is coupled to a second flow control element
5 104, which, in the experimental apparatus employed by the inventors allows for additional adjustability of flow rates. Flow control 104 is coupled to the luer lock 22, illustrated in Figure 1, which in turn is in fluid communication with electrode 14 (Figure 1), allowing delivery of Ringer's solution to the electrode. An electrosurgical generator 200 for providing R-F electrical energy is illustrated in
10 functional block form, coupled to electrical connector 24 and to a ground plate electrode 202 (not drawn to scale). All other labeled elements correspond to those illustrated in Figure 1.

While the embodiment illustrated above requires a second element (e.g. a guide catheter or guide wire) for advancing and positioning the catheter at its
15 desired location, it is anticipated that the basic apparatus disclosed above may also be incorporated into catheters which themselves are steerable or deflectable, similar to R-F ablation catheters presently in clinical investigation. Similarly, it is anticipated that in commercial embodiments, alternative mechanisms (e.g. precision pumps) for controlling the flow of Ringer's solution may be employed.
20 Similarly, while the inventors have employed Ringer's solution, other alternative fluids may be workable as well. As such, the embodiment discussed above should be considered exemplary, rather than limiting, in conjunction with the following claims.

In conjunction with the above specification, we claim:

25

CLAIMS

1. An ablation catheter system, comprising:
an elongated catheter body having a proximal portion, a distal portion and a longitudinal lumen;
5 a hollow needle for penetrating body tissue at a desired location, mounted to a distal portion of said catheter body and having an internal lumen coupled to the lumen of said catheter body;
a source of conductive fluid, coupled to the internal lumen of said catheter body, for delivering a conductive fluid to said lumen of said catheter body;
10 a conductive electrode surface for delivering R-F energy to said desired location, mounted to said distal portion of said catheter body; and
a source of R-F electrical energy, coupled to said electrode surface.
2. A catheter system according to claim 1 wherein said hollow needle is conductive and wherein said electrode surface comprises a surface of said
15 hollow needle.
3. A catheter system according to claim 1 or claim 2 wherein said hollow needle is a helical needle.
4. A catheter system according to claim 1 or claim 2 or claim 3 wherein said fluid delivery means comprises means for delivering Ringer's solution.
- 20 5. A catheter system according to claim 4 wherein said conductive fluid delivery means comprises a reservoir containing said conductive fluid and a means for controlling fluid flow.
6. A catheter system according to claim 1 wherein said catheter body comprises a torque transfer cable, extending longitudinally along said catheter
25 body.
7. A catheter system according to claim 2 wherein said catheter body comprises a conductive torque transfer cable, extending longitudinally along said catheter body, coupled to said hollow needle and to said source of R-F energy.
- 30 8. A catheter system according to claim 2 wherein said catheter body comprises a conductive tube, extending longitudinally along said catheter body, coupled to said hollow needle and to said source of R-F energy.

9. A catheter system according to claim 1 wherein said catheter body comprises a plastic tube, extending longitudinally along said catheter body, coupled to said hollow needle and to said fluid delivery means.

10. A catheter system according to claim 1, further comprising means
5 for sensing electrical signals, coupled to said electrode surface.

11. A catheter system according to claim 1 or claim 10, further comprising means for delivering stimulus pulses, coupled to said electrode surface.

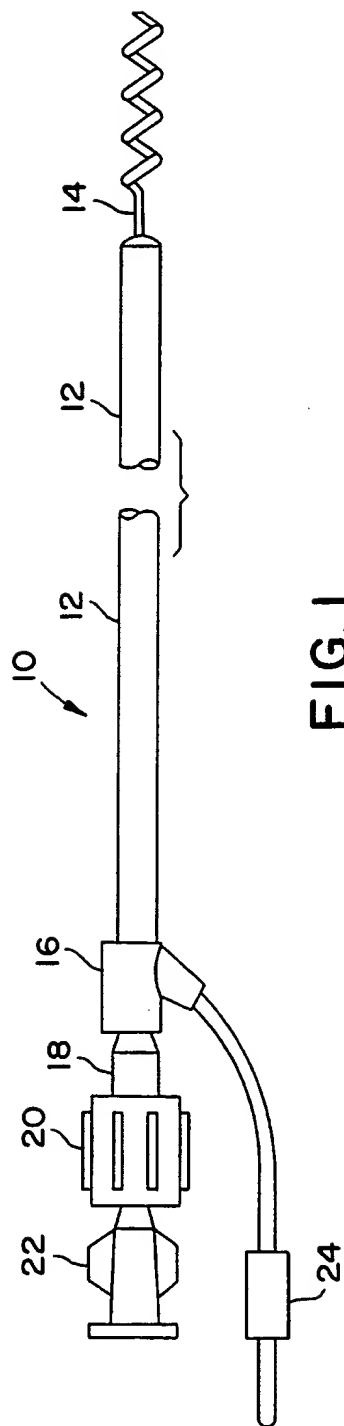


FIG. 1

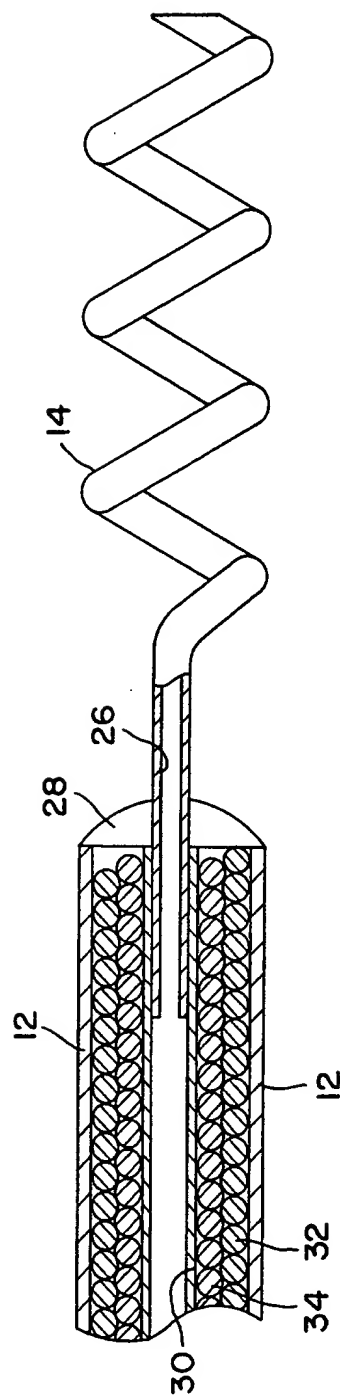


FIG. 2

2 / 3

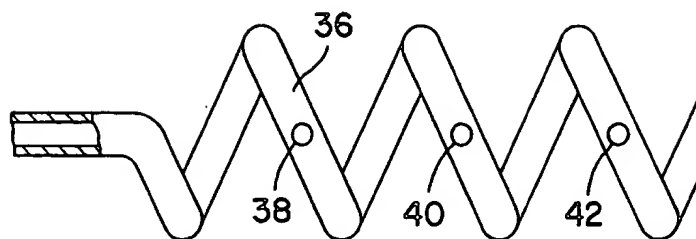


FIG. 3

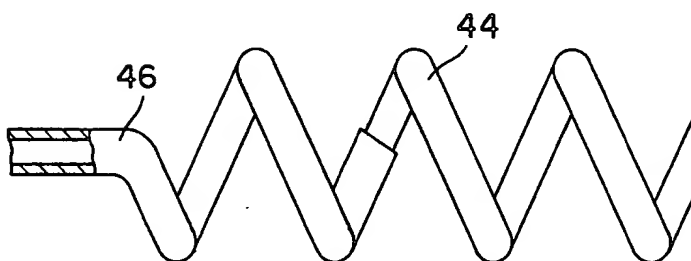


FIG. 4

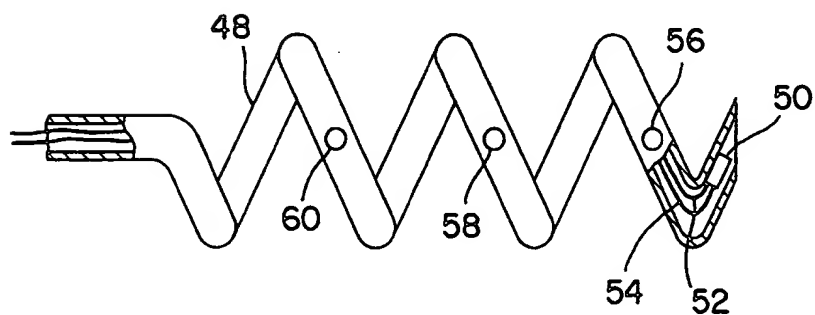


FIG. 5

3 / 3

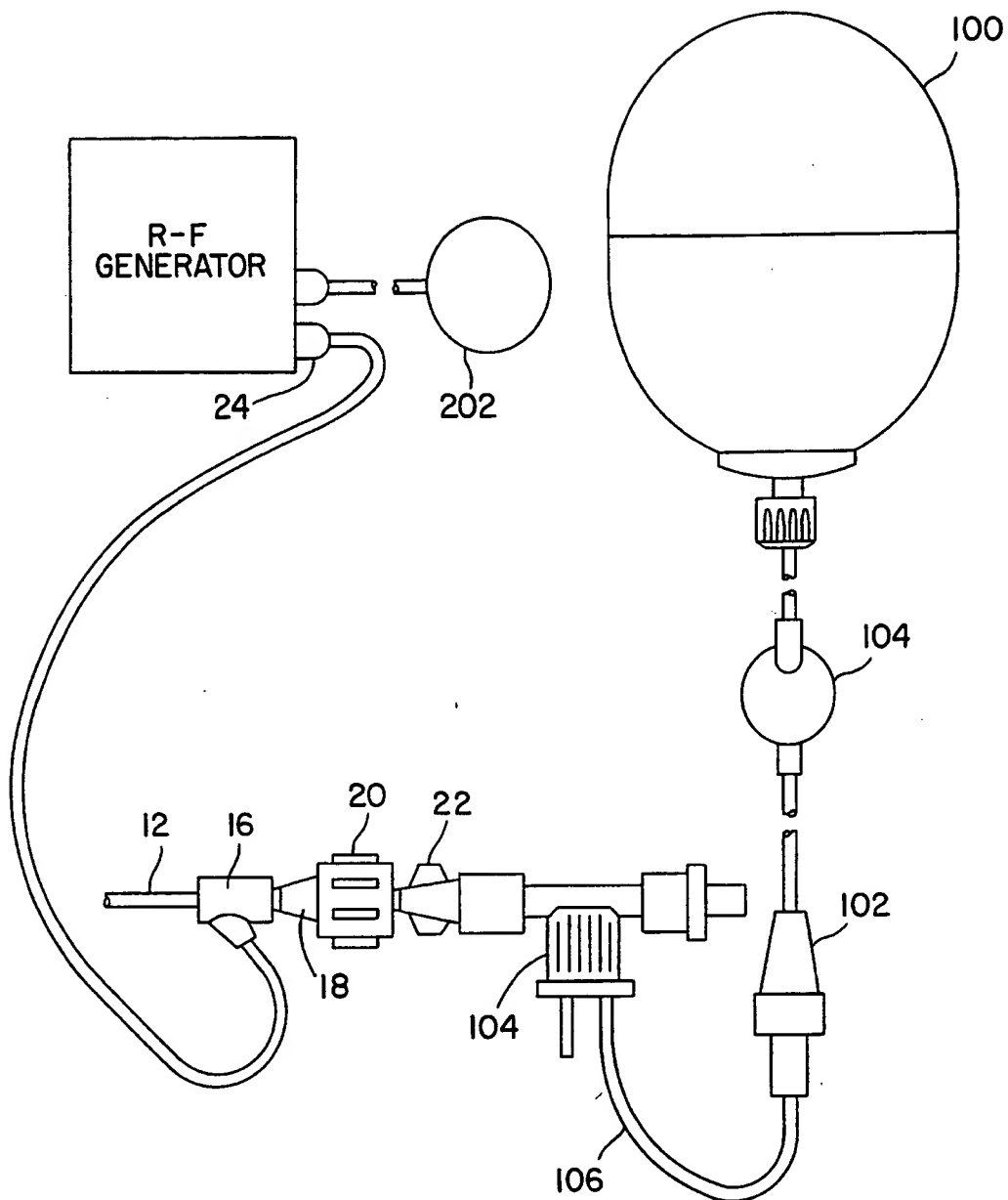


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 94/08251

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DE,C,651 428 (KOCH&STERZEL AG) 23 October 1937 see the whole document ---	1,2,4
X	US,A,4 524 770 (A ORANDI) 25 June 1985 see column 4, line 29 - line 46 see figures 1,4,5 ---	1,2,4,5
Y	FR,A,1 454 773 (ABBOTT LABS) 24 November 1964 see page 2, column 1, line 19 - line 36 ---	1,2,4
A	EP,A,0 013 605 (MEDTRONIC) 23 July 1980 -----	3,7,11

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

9 November 1994

Date of mailing of the international search report

16. 11. 94

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+ 31-70) 340-3016

Authorized officer

Vereecke, A

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US 94/08251

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-C-651428		NONE	
US-A-4524770	25-06-85	NONE	
FR-A-1454773		NONE	
EP-A-0013605	23-07-80	US-A- 4209019	24-06-80
		CA-A- 1135586	16-11-82
		JP-C- 1433747	07-04-88
		JP-A- 55094264	17-07-80
		JP-B- 62041030	01-09-87

THIS PAGE BLANK (USPTO)